



californiapharmacistsassociation

March 27, 2007

The Honorable Ellen Corbett
The Honorable Betty Karnette
The Honorable Laura Richardson
The Honorable Julia Brownley

Re: Senate Bill 472(Corbett), Assembly Bill 1276 (Karnette),
Assembly Bill 1399 (Richardson) and Assembly Bill 851 (Brownley)
Prescription Drug Labels and Insert

Dear Senator Corbett and Assembly Members Karnette, Richardson and Brownley:

I am writing on behalf of the California Pharmacists Association (CPHA) regarding the prescription drug labeling bills each of you has introduced. CPHA believes that each of your bills addresses the important issue of providing the most useful information in the most appropriate format to the consumers in question. Indeed, these concerns are reflected in the recently released findings of the Medication Errors Panel, of which CPHA was a participant.

It is our desire to work with you to find a way to address the concerns set forth in your bills. At the same time, we know you can appreciate that a prescription drug label can only accommodate so much information and that additional information and formatting raise logistical and financial issues, particularly for small, independent pharmacies. In fact, all pharmacies are facing severe financial challenges with changes to the Medi-Cal reimbursements on the horizon and the shortcomings of Medicare Part D.

In light of all of these considerations, we believe that it would make sense for all of us to work together on the labeling issues. Therefore, we ask that a meeting of stakeholders be convened under your auspices to develop a plan for addressing the issues in each of your bills.

We look forward to working with you to improve the protection of consumers on California and to enhance medical outcomes.

Sincerely,

Kathleen Lynch
Vice President of Government Affairs

cc: Senate Business, Professions and Economic Development Committee
Senate Health Committee
Assembly Business and Professions Committee
Assembly Health Committee

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CALIFORNIA SOCIETY OF
HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

April 9, 2007

Ms. Virginia Herold, Executive Officer
State Board of Pharmacy
1625 N. Market Boulevard
Sacramento, CA 95834

Dear Giny:

The California Society of Health-System Pharmacists (CSHP) would like to inform the Board of Pharmacy of our approach to the four labeling bills being addressed in the State Legislature (AB 851, AB 1276, AB 1399 and SB 472). Currently, CSHP has taken a position of "Watch" on these bills.

Given that all four labeling bills address different aspects related to the SCR 49 (Speier) Medication Errors Panel recommendations CSHP, in collaboration with the California Pharmacists Association (CPhA), approached Senator Ellen Corbett (D-San Leandro) to request she amend SB 472 to create an expert panel that would address all prescription drug labeling issues. CSHP drafted the attached language, which expresses our interest in having the issue of "labeling" addressed in a larger context whereby all stakeholders would have input on what requirements may be necessary, if at all, to ensure patient safety and provide optimal outcomes for pharmacists, physicians and consumers.

On April 3, CSHP, in part with other stakeholders, met with the co-sponsors of SB 472 (i.e. Latino Coalition for a Healthy California and Gray Panthers California) to provide input on language that resembles the intent behind CSHP's proposed language. CSHP was soon informed thereafter that the co-sponsors will add comments that came from the April 3 discussion into SB 472, which could be submitted prior to the next policy committee hearing.

If you have any questions, please do not hesitate to contact Bryce W.A. Docherty, CSHP's legislative advocate at (916) 446-4343 or me at (916) 447-1033.

Founded in 1962, CSHP represents nearly 4,000 pharmacists and associates who serve patients and the public through the promotion of wellness and rational drug therapy. CSHP members practice in a variety of organized healthcare settings, including, but not limited to, hospitals, integrated healthcare systems, clinics, home healthcare and ambulatory care settings.

Respectfully,

Dawn Benton
Executive Vice President/CEO

(Attachment)

cc: Bryce W.A. Docherty, The Docherty Group

**Reducing Medication Errors:
Health Care Literacy and Prescription Labeling**

SECTION 1. This act shall be known and may be cited as the California Patient Medication Safety Act.

SECTION 2. The Legislature hereby finds and declares all of the following:

(a) The people of California recognize the importance of reducing medication related errors and increasing health care literacy of prescription drugs and prescription container labeling that can increase consumer protection and improve their health, safety and wellbeing.

(b) The Legislature affirms the importance of identifying deficiencies in and opportunities for improving patient medication safety systems for the purpose of identifying and encouraging the adoption of structural safeguards.

(c) The Legislature intends to improve communication between patients and health care professionals as a means of reducing medication related errors and improving health care outcomes.

SECTION 3. Section 4076.5 is added to the Business and Professions Code, to read:

4076.5. (a) The board, in conjunction with Medical Board of California, and in consultation with professionals in the field, shall review issues and problems surrounding prescriber to pharmacist and pharmacist to patient and prescriber to patient communication regarding the condition for which a drug was prescribed and the intended purpose of the drug, including any off-label use, and prescriber dispensing of drugs, including samples, as well as informed consent for treatment. The review shall include, but need not be limited to, all of the following:

(1) The appropriate level of detail required on the prescription transmission and prescription container label that addresses, at a minimum, all of the following:

- (A) Diagnosis
- (B) Medical Condition
- (C) Symptoms
- (D) Indicators of the intended use of the drug
- (E) Allowance for exemptions

(2) The appropriate level of documented approval or disapproval of the patient to the intended purpose of the drug being included on the prescription or prescription container label.

(3) The appropriate level of language translation services that are available to the prescriber and pharmacist.

(4) The appropriate level of medication packaging, dispensing systems, and written supplemental materials that that effectively communicate to the consumer accurate, easy-to-understand information about the risks, and benefits of their medication, and how and where to obtain medication consultation from a pharmacist.



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Attachment

(5) Best practices to develop evidence-based standards of care for medication therapy management programs and incentives for their implementation and ongoing use by pharmacists and other health care providers.

(6) On or before January 1, 2010, the board and the Medical Board of California shall promulgate regulations to implement changes determined to be necessary with regard to those issues enumerated in subdivision (a) pertaining to prescriber to pharmacist and pharmacist to patient and prescriber to patient communication regarding the condition for which a drug was prescribed and the intended purpose of the drug, including any off-label use, and prescriber dispensing of drugs, including samples, as well as informed consent for treatment.